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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,222	09/08/2003	Morton M. Mower	06809.0030-00000	1067

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,222	MOWER, MORTON M.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☒ Claim(s) *26,37 and 49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03082004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 3/8/2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because several of the documents are missing publication dates and several of the documents less than one year old are lacking publication months. It has been placed in the application file, but some of the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

It is suggested that the headings not be underlined or bolded.

Claim Objections

1. Claims 26, 37 and 49 are objected to because of the following informalities: "ventricle" should be omitted in claim 26, "or" should be inserted between "septum" and "applying", and "contract" should read "contraction" in claim 49. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 22 recites the limitation "the at least one pulse" in the system of claim 19. There is insufficient antecedent basis for this limitation in the claim.

4. Claims 24-45 and 48-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims specify stimulating the heart from locations "in the left ventricle". Applicant discloses that "installing a similar lead into the left ventricle may create a danger to the patient due to the possibility of a thrombus being generated", and further discloses an exemplary embodiment in Fig. 4 in which the leads are placed around or on the left ventricle. It is unclear whether applicant is claiming electrodes placed in the ventricle, on the ventricle, or both. Examiner is interpreting the claims to be directed to electrodes placed on the ventricles, as is customary in the art, and as claimed in claim 52. Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23 and 45 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims comprise electrodes implanted in the heart. This implies that the invention comprises a portion of the human anatomy,

which is non-statutory subject matter. It is suggested that applicant claims electrodes "adapted to be" implanted in the heart.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4-12, 18-26, 29-32, 35, 41, 42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (5,174,289).

8. In regards to claims 1, 19, 20 and 23, Cohen discloses a device/method comprising endocardially receiving signals from the heart, determining the progress of contraction, and stimulating a chamber of the heart at a plurality of locations based on the progress (claim 1).

9. In regards to claim 2, atrial depolarization signals are sensed (col. 21, line 1).

10. In regards to claims 4 and 5, ventricular depolarization signals are sensed (col. 21, line 1) from multiple locations (col. 19, line 51).

11. In regards to claim 6, two signals are analyzed and the delay between them is determined (claim 29). It is inherent that the delay between senses is determined because a pace is initiated if a delay interval between senses is exceeded. Therefore, the delay would have to be sensed to determine if the delay interval is exceeded.

12. In regards to claims 7 and 8, a stimulation signal is applied at a first site and a second signal is selectively applied to a second location if an intrinsic electrical threshold is not exceeded (claim 29).

13. In regards to claim 9, the second signal can be applied simultaneously with the first (col. 19, line 28).

14. In regards to claims 10, 11 and 12, the stimulated locations are along a short axis (Fig. 28, elements 33-32) and a long axis (Fig. 28, elements 33-30) of the heart chamber, and at least three locations are stimulated (Fig. 28).

15. In regards to claims 21 and 22, the signal voltage and pulse width are variable (col. 19, line 7).

16. In regards to claims 24 and 25, Cohen's invention stimulates a plurality of locations in and on the left ventricle based on the timing of the received signals and the progress of contraction (Fig. 11).

17. In regards to claims 29-32, 35, 41, 42, and 44, left ventricular epicardial electrodes are used to perform the disclosed method above (col. 24, line 17).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claim 3 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen. Cohen discloses that his invention can be applied to the atrial chambers as well as the ventricular chambers (col. 24, line 25). Alternatively, it is well known in the art to sense signals from multiple areas of the atria to more vividly sense depolarization of the chamber. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Cohen's invention by sensing from multiple locations in the atrium to more vividly sense depolarization of the chamber.

20. Claims 27, 33, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Helland (5,385,579). Cohen discloses the invention using epicardial electrodes except for providing epicardial electrodes implanted in the epicardial wall. Helland teaches of epicardial electrodes implanted in the epicardial wall to provide better anchoring. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Cohen's invention with electrodes implanted in the epicardial wall to provide better anchoring.

21. Claims 13, 14, 17, 36, 37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Prystowsky et al. (4,554,922). Cohen discloses the essential features of the claimed invention except for applying either an anodal or cathodal sub-threshold pre-excitation voltage with a current of about 10 mA. Prystowsky et al. teach of applying a sub-threshold pre-excitation voltage of about 10 mA (col. 5, line 48) to inhibit arrhythmic beats (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

provide Cohen's invention with a sub-threshold pre-excitation voltage of about 10 mA to inhibit arrhythmic beats.

22. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Prystowsky as applied to claim 13 above, and further in view of Altman (5,551,427). The modified invention of Cohen in view of Prystowsky discloses the essential features of the claimed invention except for an electrode implanted in the interventricular septum. Altman teaches of implanting a septal electrode using a helical wire to provide better fixation and stimulation of the left ventricle. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention taught by Cohen in view of Prystowsky by implanting the electrode in the interventricular septum, using a helical wire, to provide better fixation and stimulation of the left ventricle.

23. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Smits (4,641,656). Cohen discloses the essential features of the claimed invention except for providing an electrode in the coronary vasculature. Smits teaches of providing an electrode in a coronary vein to allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field to be sensed and applied to the left ventricle (Fig. 15). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Cohen's invention with an electrode in a coronary vein to allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field to be sensed and applied to the left ventricle.

24. Claim 34, 38, 39, 45, 46, 47, 51, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Smits, and further in view of Altman. Cohen discloses the essential features of the claimed invention except for providing an electrode in the coronary vasculature and implanting an electrode in the interventricular septum. Smits teaches of providing an electrode in a coronary vein to allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field to be sensed and applied to the left ventricle, and Altman teaches of implanting a septal electrode using a helical wire to provide better fixation and stimulation of the left ventricle. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Cohen's invention with an electrode in a coronary vein to allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field to be sensed and applied to the left ventricle and a septal electrode implanted using a helical wire to provide better fixation and stimulation of the left ventricle.

25. Claims 48-50, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Smits, Altman, and Prystowsky et al. Cohen discloses the essential features of the claimed invention except for applying a pre-excitation voltage to the stimulation site, providing an electrode in the coronary vasculature and implanting an electrode in the interventricular septum. Prystowsky et al. teach of applying a sub-threshold pre-excitation voltage to inhibit arrhythmic beats, Smits teaches of providing an electrode in a coronary vein to allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized

electric field to be sensed and applied to the left ventricle, and Altman teaches of implanting a septal electrode using a helical wire to provide better fixation and stimulation of the left ventricle. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Cohen's invention by applying a pre-excitation voltage to the stimulation site, providing an electrode in the coronary vasculature and implanting an electrode in the interventricular septum to inhibit arrhythmic beats, allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field to be sensed and applied to the left ventricle, and provide better electrode fixation and stimulation of the left ventricle.

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Other examples of left ventricle stimulators are provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571)272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GEORGE R. EVANISKO
PRIMARY EXAMINER
10/4/5

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10/4/05